



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Stryker Endoscopy
% Underwriters Laboratories, Incorporated
Mr. Ned Divine
Senior Staff Engineer
333 Pfingsten Road
Northbrook, IL 60062

JUL 27 2015

Re: K121893
Trade/Device Name: Stryker SDC3 HD Information Management System (SDC3)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ, HRX
Dated (Date on orig SE ltr): August 17, 2012
Received (Date on orig SE ltr): August 21, 2012

Dear Mr. Divine,

This letter corrects our substantially equivalent letter of September 5, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure



Stryker Endoscopy

Traditional 510(k) Premarket Notification
SDC3 HD Information Management System

SECTION 4

INDICATIONS FOR USE STATEMENT

INDICATIONS FOR USE STATEMENT

Device Name: Stryker SDC3 HD Information Management System (SDC3)

510(k) Number (if known): K121893

Indications for Use:

The Stryker SDC3 HD Information Management System (SDC3) is intended for use with compatible endoscopic and general surgery devices. SDC3 can be used in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery wherever a laparoscope, endoscope, or an arthroscope is indicated for use. A few examples of the more common endoscopic surgeries are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic & thorascopic anterior spinal fusion, anterior cruciate ligament reconstruction, knee arthroscopy, shoulder arthroscopy, small joint arthroscopy, decompression fixation, wedge resection, lung biopsy, pleural biopsy, dorsal sympathectomy, pleurodesis, internal mammary artery dissection for coronary artery bypass, coronary artery bypass grafting where endoscopic visualization is indicated and examination of the evacuated cardiac chamber during performance of valve replacement. SDC3 users are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, and urologists.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – COUNTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden, M.D.
(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121893

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1. General Information

510(k) Sponsor:	Stryker Endoscopy
Address:	5900 Optical Court San Jose, CA 95138
FDA Registration Number:	2936485
Correspondence person:	Lifei Liu, RAC Senior Regulatory Affairs Analyst Stryker Endoscopy Email: lifei.liu@stryker.com Phone: (408) 754-2315

2. Device Identification**Proposed Device:**

Proprietary Name:	Stryker SDC3 HD Information Management System
Classification Name:	Laparoscope, General and Plastic Surgery
Regulation Number:	21 CFR 876.1500
Product Code:	GCI
Subsequent Product Codes:	HRX, KOG
Regulatory Class:	II

Predicate Device:

Proprietary Name:	Stryker SIDNE™ System
Premarket Notification	K022393
Classification Name:	Laparoscope, General and Plastic Surgery
Regulation Number:	21 CFR 876.1500
Product Code:	GCI
Subsequent Product Codes:	HRX, KOG
Regulatory Class:	II

3. Device Description

The Stryker SDC3 HD Information Management System (referred to as "SDC3 system" in the following sections) is a medical device that allows the surgeon to control the state, selection, and settings of any compatible device attached to it. It also has operating room documentation functionalities (Class I device function) to electronically capture, transfer, store and display medical device data independently of the functions or parameters of any connected medical device.

4. Indications for Use

The SDC3 system is intended for use with compatible endoscopic and general surgery devices. SDC3 can be used in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery wherever a laparoscope, endoscope, or an arthroscope is

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indicated for use. A few examples of the more common endoscopic surgeries are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic & thorascopic anterior spinal fusion, anterior cruciate ligament reconstruction, knee arthroscopy, shoulder arthroscopy, small joint arthroscopy, decompression fixation, wedge resection, lung biopsy, pleural biopsy, dorsal sympathectomy, pleurodesis, internal mammary artery dissection for coronary artery bypass, coronary artery bypass grafting where endoscopic visualization is indicated and examination of the evacuated cardiac chamber during performance of valve replacement. SDC3 users are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, and urologists.

The Indications for Use for the SDC3 system is identical to the Indications for Use previously cleared for the Stryker SIDNE™ System (K022393).

5. Intended Use

The intended use of the SDC3 system is to allow for voice control and remote control of medical device settings by the surgeons or operating room personnel, thereby eliminating the need of manual operation of those devices compatible with SDC3, or relying upon verbal communications between the surgeon and other personnel in the operating room in order to adjust the surgical equipment. It also has an additional digital documentation functionality to electronically capture, transfer, store and display medical device data (Class I device function), which is independent of the functions or parameters of any attached device.

The only difference between the Intended Use of the SDC3 system and the Stryker SIDNE™ System is the addition of digital documentation functionality (Class I device function) to the SDC3 system. Addition of such functionality does not render SDC3 system exceeding the limitations set forth in 21 CFR 876.1500, nor does it impact the safety and effectiveness for the intended use of device control. As a result, the Intended Use of the SDC3 system and the Stryker SIDNE™ System is deemed to be the same based on FDA guidance "510(k) 'Substantial Equivalence' Decision Making Process".†

†<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134783.htm>

6. Technological Comparison

The SDC3 system has similar hardware as the predicate device, uses the same communication protocols as the predicate device, employs the same voice recognition technology and controls the same types of connected devices as the predicate device. Therefore, the SDC3 has the same technological characteristics as the predicate device in the following areas:

- Operating principle
- Software architecture
- Electrical characteristics
- Mechanical characteristics
- Communication characteristics

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- Performance characteristics
- Compatibility with controllable devices as listed in the product labeling
- Energy source
- Material (no patient contacting material)

7. Performance Testing

The SDC3 System was tested for performance in accordance with internal design specifications and with the applicable performance standards. Risk analysis was carried out in accordance with ISO 14971:2007; subsequently design verification/validation activities and corresponding acceptance criteria were identified and performed in accordance to the risk analysis assessment. The performance testing for design verification and validation is as follows:

- Verification/validation testing for voice recognition performance
- Verification/validation testing for device control performance
- Verification/validation testing for digital documentation performance
- Verification/validation testing for environmental performance evaluation

Electrical safety and electromagnetic compatibility testing was performed in accordance to IEC 60601-1:1988/A1:1991/A2:1995 and IEC 60601-1-2: 2001 + A1: 2004, respectively. Testing indicates that the SDC3 System conforms to the aforementioned voluntary standards.

The software validation activities were performed in accordance with IEC 62304:2006 as well as the FDA Guidance documents, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", "Off-The-Shelf Software Use in Medical Devices", and "Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software". The testing for the software verification and validation activities is as follows:

- Unit level testing
- Integration level testing
- System level testing and simulated use testing

8. Conclusion

The SDC3 system has the following similarities as compared to its predicated device:

- Identical indications for use,
- Same Intended Use
- Same technological characteristics

In conclusion, the Stryker SDC3 system raises no new questions of safety and effectiveness as compared to its predicate device. Therefore, the SDC3 system is substantially equivalent to the predicate device the Stryker SIDNE™ system.